Registration of controlled drugs

1062. SHRI RAJNI RANJAN SAHU:
DR. (SHRIMATI) SAROJINI MAHISHI:

Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether controlled release preparations are considered new drugs or are covered under cleared drugs;

(b) what are the details of authority to register control release preparations for marketing in the country;

(c) whether it is a fact that different state licensing authorities adopt different norms for granting manufacturing permissions of such preparations; and

(d) what criteria are adopted by the Central Government for granting permission of controlled release preparations?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) Control release preparations are considered 'new' drugs as per the "Guidelines for Introduction of New Drugs", which is yet to become statutory;

(b) All drugs considered new are required to be cleared by the Drugs Controller (India).

(c) and (d) Since the "Guidelines for Introduction of New Drugs" is not yet statutory, different State Drug Controllers have granted permission to manufacture control release preparations of old drugs.

The requirements for obtaining permission for control release formulations include in-vitro dissolution studies, in-vivo blood level studies and/or therapeutic trials and any co-relation that may exist between in-vitro and in-vivo studies.

Sale of drugs without prescription

1063. SHRI RAJNI RANJAN SAHU: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that many drugs are easily available in the markets without prescription;

(b) whether this practice is going on due to non-control over drug advertisements in the press; and

(c) if so, what steps Government propose to take to curb this practice?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAROJ KHAPARDE): (a) The drugs listed in Schedule H and Schedule X to the Drugs & Cosmetic Rules 1945 are required to be sold by a retail chemist only under the personal supervision of a "Qualified Person" and against the prescription of a Registered Medical Practitioner. All other drugs can be said without prescription of a Registered Medical Practitioner.

(b) and (c) Advertisements of drugs are controlled under the provisions of the Drugs and Magic Remedies (Objectional Advertisements) Act. Under this Act, no one can advertise any drug for the treatment of 55 diseased listed in the Schedule to the Act.

राज्यों में पर्यटन की प्रगति

1064. **श्री मोर्जा इशाबिग :** क्या नागर विमानन और पर्यटन मंत्री यह बताने की कृपा करेंगे कि :

(क) पर्यटन के विकास के संबंध में प्रत्येक राज्य में चल रही योजनाओं का ब्यौरा क्या है और इस संबंध में अन्य योजनायें क्या हैं ; और

(ख) चालू वर्ष के दौरान इस संबंध में गुजरात में क्या कार्य किया जायेगा ; क्या शामलाजी, (साबरकांठा) और इडर को पर्यटन विकास के कार्य क्षेत्र में शामिल

करने के संबंध में कोई सर्वेक्षण किया गया है , यदि हां, तो इस संबंध में ब्यौरा क्या है और यह कार्य कब तक आरम्भ किये जाने की संभावना है ?

नागर विमानन और पर्यटन मंत्रालय के राज्य मंत्री (श्री शिवराज पाटिल) : (क) केन्द्रीय पर्यटन मंत्रालय राज्य सरकारों से प्राप्त विशिष्ट प्रस्तावों के आधार पर पर्यटक केन्द्रों पर पर्यटन आधारिक-संरचना का सृजन करने हेतु राज्यों को वित्तीय सहायता प्रदान करता है । इस मंत्रालय की अनुमोदित प्लान स्कीमों के दायरे में होने पर ही परियोजना के लिये वित्तीय सहायता प्रदान की जाती है । विभिन्न राज्यो मे इस मंत्रालय की कुछ प्रमुख स्कीमें प्रगति पर हैं जिनमे सांस्कृतिक, पर्यटन समुद्र-तट पर्यटन, वन्य जीव पर्यटन, यात्री निवास सामाजिक, पर्यटक पर्यटक केन्द्रों पर आधारिक संरचना का विकास, साहसिक पर्यटन, आदि से संबंधित स्कीमे शामिल हैं ।

(ख) किसी खास वर्ष में राज्यों में किस प्रकार की परियोजनायें शुरू करनी हैं । मंत्रालय इस बारे मे पहले से निर्णय नहीं लेता है । राज्य सरकारों द्वारा वित्तीय सहायता हेतु भिजवाये गये प्रस्तावों पर स्थान की संभाव्यता, विद्यमान तथा भावी पर्यटक यातायात, परियोजना की व्यवहार्यता, प्रस्ताव के समग्र गुणों, निधियों की उपलब्धता तथा परस्पर प्राथमिकता पर निर्भर रहते हुये विचार किया जाता है । पर्यटन केन्द्रों को पर्यटन विकास की परिधि में शामिल करने हेतु विशिष्ट सर्वेक्षण संबंधित राज्य सरकारों द्वारा कराये जाते हैं और फिर सर्वेक्षण के निष्कर्षों को ध्यान में रखते हुये वे केन्द्रीय वित्तीय सहायता हेतु प्रस्ताव तैयार करती है ।

Price Control of the Vaccines

1065. SHRI CHANDRIKA PRASAD TRIPATHI: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Diptheria, Tetanus, Pertussis, Triple Antigen are indigenously produced and the country has attained self-sufficiency and there have been no imports during the last four years, if so, on what basis these vaccines have not been included under price control under the pretext of non-availability;

(b) whether Government have taken up the matter with the Department of Chemicals for inclusion of these vaccines under price control;

(c) whether it is a fact that Government was the party to the policy decision in regard to price control of drugs needed for National Health Programmes;

(d) if so, the date when these vaccines are used for immunisation Programme;

(e) whether Government has taken up the matter for inclusion; and

(f) if so, what are the developments and by when the same are likely to be included?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (KUMARI SAFKHAPARDE): (a) to (f) Inform available with the Government that there has been no import of le Antigen (Diptheria, Tetanus a Pertussis) during the last 4 years.

One of the exclusion criteria adopted by the Kelkar Committee was that to exclude those life saving drugs and pharmaceutical products whose availability is far more important than the price, as the nature of demand is such that they are required less frequently but their non-availability is fatal. The notable examples of such categories are sera and vaccines, however, Ministry of Health and Family Welfare have recommended for inclusion of vaccines required under E.P.I. programme under price control to the Department of Chemicals, a Ministry of Health and Family Welfare monitors the activities falling under the National Health Programmes. The Immunisation programme has been in existence for many years